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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/612,079   | 07/02/2003  | Ray C. Wasielewski   | ORW01-GN003         | 5826             |
| 30074  | 7590        | 08/01/2006           | EXAMINER            |                  |
| TAFT, STETTINIUS & HOLLISTER LLP<br>SUITE 1800<br>425 WALNUT STREET<br>CINCINNATI, OH 45202-3957 |             |                      | RAMANA, ANURADHA    |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3733                |                  |

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/612,079

Applicant(s)

WASELEWSKI, RAY C.

Examiner

Anu Ramana

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) 77-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41, 45-63, 65-76 and 105 is/are rejected.
- 7) ☒ Claim(s) 42-44 and 64 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/6/03.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

Applicant's election without traverse of the invention of Group I (claims 1-76 and 105) in the reply filed on April 11, 2006 is acknowledged. Accordingly, claims 1-76 and 105 have been examined on the merits in this office action.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7-14, 17, 20, 41, 45-54, 57, 58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Davidson (US 5,458,653).

Davidson discloses a coating or lining made of a bioabsorbable polymer such as polyglycolic or polylactic acid wherein the lining may also include growth factors, osteogenic materials and antibiotics (col. 3, lines 41-59, col. 6, lines 53-67 and col. 7, lines 1-9).

Claims 1-3, 5-6, 7-15, 17, 20, 23-25, 27-28, 29-34 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Tormala et al. (US 6,113,640).

Tormala et al. discloses a strip of fabric or lining that can be fixed to a bone by a bioabsorbable fastener such as a pin (Figs. 1, 11A, 11B, col. 4, lines 30-55, col. 6, lines 62-67, col. 7, lines 1-19 and col. 8, lines 8-21).

Claim 105 is rejected under 35 U.S.C. 102(b) as being anticipated by Engelbrecht et al. (US 4,790,853).

Engelbrecht et al. disclose a knee-joint prosthesis including a tibial component, a femoral component and a lining 40 positioned between the tibial and the femoral components (Figs. 1 and 2, col. 4, lines 36-56 and col. 6, lines 23-31).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 16, 18, 19, 21, 22, 55, 56, 58, 59, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (US 5,458,653) in view of Scarborough (US 6,616,698).

Davidson discloses all elements of the claimed invention except for an antibiotic agent such as gentamicin, a clotting factor and osteogenic materials such as stem cells and transforming growth factor.

It is very well known to use gentamicin as an antibiotic and osteogenic materials such as stem cells and transforming growth factor in implants as evidenced by Scarborough (col. 6, lines 17-55).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used an antibiotic such as gentamicin and osteogenic materials such as stem cells and transforming growth factor in the Davidson implant, since it was well known to use these materials for their intended purpose, namely, promoting bone growth and prevention of infection.

Claims 16, 18-19, 21-22, 35-37, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. (US 6,113,640) in view of Scarborough (US 6,616,698).

Tormala et al. disclose all elements of the claimed invention except for an antibiotic agent such as gentamicin and osteogenic materials such as stem cells and transforming growth factor.

It is very well known to use gentamicin as an antibiotic and osteogenic materials such as stem cells and transforming growth factor in implants as evidenced by Scarborough (col. 6, lines 17-55).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used an antibiotic such as gentamicin and osteogenic materials such as stem cells and transforming growth factor in the Tormala et al. implant, since it was well known to use these materials for their intended purpose, namely, promoting bone growth and prevention of infection.

Claims 4 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. (US 6,113,640) in view of Felt et al. (US 2002/0173852).

Tormala et al. disclose all elements of the claimed invention except for fasteners such as screws.

Felt et al. teach the equivalence of pins and screws (para [0079]).

It would have been obvious to one of ordinary skill in the art to substitute a screw as, for example, taught by the Felt et al. reference for the pin of the Tormala et al. device wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these structures would work equally well in the Tormala et al. device.

Claims 63 and 65-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helfet (RE 29,757) in view of Valentini (US 5,759,205).

Helfet discloses a knee joint prosthesis including a femoral component 16, a tibial component 17 and a lining mounted to a stabilizing post of the tibial component wherein the lining is made of a synthetic resin plastic material (Fig. 7, col. 3, lines 6-68 and col. 4, lines 1-30).

Helfet discloses all elements of the claimed invention except for the lining being made of a biologic material.

Valentini teaches natural and synthetic materials that are biocompatible and/or biodegradable (col. 6, lines 55-67 and col. 7, lines 1-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the synthetic resin material of Helfet with a biologic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein biocompatibility, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Allowable Subject Matter***

Claims 42-44 and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR  
July 24, 2006

A handwritten signature in black ink, appearing to read "Anuradha Samana". The signature is written in a cursive, flowing style.